REMARKS

Claims 11-15 and 21-23 were pending. Claim 23 is amended herein. It is believed that no new matter is added. No claim is allowed.

Applicants gratefully acknowledge the withdrawal of the rejections under 35 U.S.C. §§ 102 and 103.

Applicants also wish to acknowledge the Advisory Information provided by the Examiner. The Examiner's statement regarding the claimed antibody or an antigen-binding fragment thereof of claim 23 each specifically binding the protein of SEQ ID NO:17.

Rejection under 35 U.S.C. § 112, second paragraph

Claim 23 was rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. According to the Examiner, the claimed sequence is a polypeptide sequence and thus cannot encode a protein. Applicants respectfully traverse this rejection.

Claim 23 is amended herein to clarify the binding compounds as ones that bind the protein of SEQ ID NO:17.

In view of the above, the basis of the rejection may be removed.

Rejection under 35 U.S.C. §§ 101 and 112

Claim 11-15 and 21-22 were rejected under 35 U.S.C. §§ 101 and 112 because the claimed compositions allegedly are not supported by either a specific and substantially asserted utility or a well-established utility for reasons of record. Applicants respectfully traverse this rejection.

As a preliminary matter, Applicants gratefully acknowledge that claim 23 fulfills the requirements under 35 U.S.C. §§ 101 and 112.

Applicants again respectfully submit that the specification discloses a sufficient utility for the claimed binding compounds for reasons of record and those discussed below. First, the stated utility of modulating apoptosis is a specific and substantial utility. The Examiner asserts that this is insufficient "absent any other information", but fails to point to what information is lacking.

Apoptosis is a specific cellular process, and its induction is specifically disclosed in the specification as filed. *See, e.g.,* the specification at page 32, lines 19-21. Objective evidence demonstrates that RANKL acts to induce apoptosis. *See e.g.,* Sinha et al. (already of record). The fact that other TNF receptors also have this activity only further *supports* the credibility of this utility. The utility need not be novel, only specific, useful and credible. Moreover, apoptosis is a critical regulator of cellular proliferation and development. This is well known in the art. Thus, it cannot be summarily dismissed as insufficient under the current legal standard for utility. In other words, the ability of the disclosed molecule to fall under a known paradigm of apoptosis regulating development does not render that utility insubstantial or non-specific. It simply further supports that a person of skill in the art, when considering the evidence as a whole, would conclude that the asserted utility is *more likely than not true*. *See* M.P.E.P. § 2107.03 (II) ("An applicant is only required to provide evidence if, when considered as a whole, leads the skilled artisan to conclude that the asserted utility is more likely than not true.") (original emphasis).

Finally, Applicants note that here is no legal requirement that the disclosed utility must be supported by conclusive experimental data. According to the M.P.E.P.,

> [a]s a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

MPEP § 2107.02 (III) (A) (emphasis original). The Examiner acknowledges that the specification provides data demonstrating the upregulation of RANKL mRNA in at least two models of inflammation. That is sufficient to support the minimal requirement for utility. Applicants are not required to provide evidence sufficient to establish that an asserted utility is true "beyond a reasonable doubt" or "as a matter of statistical certainty." *See* M.P.E.P. § 2107.02 (VII).

For at least these reasons, Applicants believe the disclosure in the specification as filed meets the utility requirement of 35 U.S.C. § 101.

In view of the above, the basis of the rejection may be removed.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 140942000401. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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